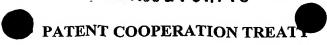
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## **PCT**



### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ONF-4571PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416		
International application No. PCT/JP2003/008039	International filing date (day/mont 25 June 2003 (25.06.20)			
International Patent Classification (IPC) or national classification and IPC A61K 45/00, 31/437, 31/445, A61P 9/00, 9/06, 9/10, 9/12, 9/14, 13/12, 25/06, 43/00, C07D 471/04				
Applicant ONO PHARMACEUTICAL CO., LTD.				
<ol> <li>This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</li> </ol>				
2. This REPORT consists of a total of		is cover sheet.		
3. This report is also accompanied by A	ANNEXES, comprising:			
a. (sent to the applicant and	to the International Bureau) a total	of sheets, as follows:		
sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).				
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.				
b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))  , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).				
4. This report contains indications rela	ting to the following items:			
Box No. I Basis of the re	eport			
Box No. II Priority				
Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
Box No. IV Lack of unity	of invention			
Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
K_2				
Box No. VII Certain defec				
Box No. VIII Certain observations on the international application				
Date of submission of the demand  Date of completion of this report				
06 January 2004 (06.01.2004)		26 September 2004 (26.09.2004)		
Name and mailing address of the IPEA/JP		Authorized officer		
Facsimile No.		Telephone No.		

Translation



#### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

## International application No.

#### PCT/JP2003/008039

Box No.	Basis of the report	
	egard to the language, this report is based on the international application in the language in which it was filed, unless rise indicated under this item.	
	This report is based on translations from the original language into the following language which is language of a translation furnished for the purpose of:	<b>-</b> ,
i i	international search (under Rules 12.3 and 23.1(b))	
	publication of the international application (under Rule 12.4)	
	international preliminary examination (under Rules 55.2 and/or 55.3)	
		18
furnis	regard to the elements of the international application, this report is based on (replacement sheets which have be need to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally file not annexed to this report):	en d"
	The international application as originally filed/furnished	
	the description:	ahad
	pages, as originally filed/furni	snea
	pages* received by this Authority on received by this Authority on	
	the claims:	ichad
	pages, as originally filed/furni pages*, as amended (together with any statement) under Artic	
	- 11 Alia A Abrilana	
	pages* received by this Authority on	
	the drawings:  pages , as originally filed/furni	iched
	pages, as originally frieuzum.  pages* received by this Authority on	isticu
	pages* received by this Authority on	
l		
ļШ	a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.	
3.	The amendments have resulted in the cancellation of:	
	the description, pages	
	the claims, Nos.	
	the drawings, sheets/figs	
	the sequence listing (specify):	
	any table(s) related to sequence listing (specify):	
1		
4.	This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).  The description, pages	n x
	the claims, Nos.	
	the drawings, sheets/figs	
	the sequence listing (specify):	
	any table(s) related to sequence listing (specify):	
* If ite	n 4 applies, some or all of those sheets may be marked "superseded."	

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

PCT/JP03/08039	

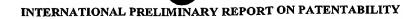
Box No. II	I Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
The quest	ions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially have not been examined in respect of:
	the entire international application.
$\boxtimes$	claims Nos
because	the said international application, or the said claims Nos. 61-65 relate to the following subject matter which does not require an international preliminary examination (specify):
which do	the subject matters of claims 61-65 relate to a method for treatment of the human body by therapy, sees not require the preliminary international examination by the Preliminary International Examining by in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).
	·
	the description, claims or drawings (indicate particular elements below) or said claims Nosare so unclear that no meaningful opinion could be formed (specify):
İ	
	the claims, or said claims Nos are so inadequately supported
	by the description that no meaningful opinion could be formed.
	no international search report has been established for said claims Nos
	the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
	the written form has not been furnished
	does not comply with the standard  the computer readable form has not been furnished
	the computer readable form has not been furnished  does not comply with the standard
	the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
	see Supplemental Box for further details.
1	



Inter	nal application No.
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PCT/JP03/08039

Box No. IV	Lack of unity of invention
1.	In response to the invitation to restrict or pay additional fees the applicant has:
	restricted the claims.
	paid additional fees.
	paid additional fees under protest.
$\boxtimes$	neither restricted nor paid additional fees.
2. T	his Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, of to invite the applicant to restrict or pay additional fees.
3. This Au	thority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
co	omplied with.
	ot complied with for the following reasons:
EDG-5 re	e technical feature of the subject matter of claim 1 is "A remedy and/or preventive comprising an egulator for the diseases caused by vasoconstriction or vasodilation," and the subject matters of claims claim 1.
(I) A-X-Y As 66-70 do	e technical feature of the subject matter of claim 10 is "A compound represented by general formula \( \begin{align*} \cdot \c
4. Conse	quently, this report has been established in respect of the following parts of the international application:
	all parts.
	the parts relating to claims Nos
1	



Claims

Claims

YES

NO

Box No. V Reasoned statement under Article 35(2) with regard to noverty, inventive step or industrial applicability; citations and explanations supporting such statement				
1. Statement				
Novelty (N)	Claims	6, 7	YES	
	Claims	1-5, 8, 9	NO NO	
Inventive step (IS)	Claims		YES	
	Claims	1-9	NO	

1-9

2. Citations and explanations (Rule 70.7)

Industrial applicability (IA)

Claims 1-5, 8 and 9

Document 1: JP, 2001-261575, & WO, 01-69252, A1

Document 1 cited in the ISR describes that an EDG-5 receptor agonist and an EDG-receptor inhibitor are used to regulate vasoconstriction (see claims 5, 29, etc.).

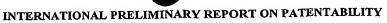
Therefore, the subject matters of claims 1-5, 8 and 9 do not appear to be novel or to involve an inventive step.

Claims 6 and 7

Document 2: WO, 01-98301, A1

Document 2 cited in the ISR describes that the compounds corresponding to general formulae (I) and (II) have EDG-5 antagonist activity. A person skilled in the art could have easily used the compounds described in document 2 as EDG receptor inhibitors in the invention described in document 1.

Therefore, the subject matters of claims 6 and 7 do not appear to involve an inventive step.



#### PCT/JP03/08039

# Box No. VI Certain documents cited 1. Certain published documents (Rule 70.10) Priority date (valid claim) Filing date Application No. Publication date (day/month/year) (day/month/year) (day/month/year) Patent No. 14.12.2001 13.12.2002 26.06.2003 W0 03/051976 A1 [E, X] 2. Non-written disclosures (Rule 70.9) Date of written disclosure referring to non-written disclosure Date of non-written disclosure Kind of non-written disclosure (day/month/year) (day/month/year)





Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The subject matters of claims 1-5, 8 and 9 relate to a remedy and/or preventive containing a compound defined by a desired nature called "EDG-5 regulator" as an active ingredient, for the diseases caused by vasoconstriction or vasodilation, and claims 1-5, 8 and 9 include all the compounds with such a nature. However, the compounds disclosed in the sense of PCT Article 5 are only a very small portion of the claimed compounds, and the claimed compounds are not supported by the disclosure of the specification in the sense of PCT Article 6.

Furthermore, since the "EDG-5 regulator" does not allow the scope of the compounds with such a nature to be identified even if the common general technical knowledge prevailing on the filing date of the present application is considered, the subject matters of claims 1-5, 8 and 9 do not satisfy the requirement of clarity in PCT Article 6.

The subject matters of claims 6 and 7 relate to "a remedy and/or preventive containing a compound defined by a desired nature called "EDG-5 regulator" as an active ingredient for the diseases caused by vasoconstriction or vasodilation. General formulae (I) and (II) include very numerous compounds. However, the compounds disclosed in the sense of PCT Article 5 are only a very small portion of the claimed compounds, and the claimed compounds are not sufficiently supported in the sense of PCT Article 6.